

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA,) **Case No. 3:15-CR-0496-L**
)
Plaintiff,)
) Dallas, Texas
v.) September 7, 2016
) 9:00 a.m.
SK LABORATORIES, INC. (06))
AND SITESH PATEL (07),) MOTION TO MODIFY CONDITIONS
) OF RELEASE [133]
Defendants.)

TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE PAUL D. STICKNEY,
UNITED STATES MAGISTRATE JUDGE.

APPEARANCES:

For the Government: David O'Donald Sullivan
Patrick Raymond Runkle
UNITED STATES DEPARTMENT OF JUSTICE
CONSUMER PROTECTION BRANCH
P.O. Box 386
Washington, DC 20044-0386
(202) 514-0516

For Defendant SK Laboratories, Inc.: Joseph Mark McMullen
LAW OFFICES OF JOSEPH M. MCMULLEN
225 Broadway, Suite 1460
San Diego, CA 92101
(619) 501-2000

For Defendant Patel: Patrick Quinn Hall
Law Offices of Patrick Q. Hall
401 B Street, Suite 2220
San Diego, CA 92101
(619) 268-4040

For Defendant Patel: Chris Niewoehner
STEPTOE & JOHNSON, LLP
115 South LaSalle Street, Suite
3100
Chicago, IL 60603
(312) 577-1240

1 Court Recorder: Lavenia Price
2 UNITED STATES DISTRICT COURT
3 1100 Commerce Street, Room 1549
4 Dallas, TX 75242-1003
5 (214) 753-2168

6 Transcription Service: Kathy Rehling
7 311 Paradise Cove
8 Shady Shores, TX 76208
9 (972) 786-3063
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

25 Proceedings recorded by electronic sound recording;
transcript produced by transcription service.

1 DALLAS, TEXAS - SEPTEMBER 7, 2016 - 9:04 A.M.

2 THE COURT: Court is in session in the matter of
3 United States of America v. SK Laboratories and Sitesh Patel,
4 3:15-cr-496-L. Who's here for the Government?

5 MR. RUNKLE: Patrick Runkle from the Consumer
6 Protection Branch of the Department of Justice, Your Honor.

7 MR. SULLIVAN: David Sullivan from the same, Your
8 Honor.

9 THE COURT: Thank you. For the Defense?

10 MR. HALL: Patrick Hall on behalf of Sitesh Patel,
11 Your Honor. He's seated here in the first row, with the
12 Court's permission, if that's acceptable.

13 THE COURT: Yes, that's fine.

14 MR. MCMULLEN: Good morning, Your Honor. Joseph
15 McMullen for SK Laboratories.

16 THE COURT: All right. Thank you. Is the Government
17 ready to proceed?

18 MR. RUNKLE: Yes, we are, Your Honor.

19 THE COURT: Defense?

20 MR. HALL: Yes, Your Honor.

21 MR. MCMULLEN: Yes, Your Honor.

22 THE COURT: I'm happy to hear from you.

23 MR. RUNKLE: Thank you, Your Honor. And we really
24 appreciate the opportunity and your indulgence in having this
25 hearing today.

1 THE COURT: Yes, sir.

2 MR. RUNKLE: Now, what's facing the Court here is a
3 simple question that can't and shouldn't be obscured by the 700
4 pages of filings that the Defendants filed. And none of those
5 pages of filings answer the real question here, and that is,
6 should the Defendant that's implicated in three different
7 clusters of injuries from three different dietary supplements,
8 facing decades in federal prison for hurting people, be allowed
9 to continue operations just because they say he's a nice guy?
10 The answer is of course not. In their filings, they complain
11 over and over again that the Government is misusing the bond
12 statute, could file an injunction action, and all sorts of
13 other things about the improper misuse of the conditions of
14 release. But how is it misuse of the bond statute to try to
15 protect the public from two indicted defendants who are
16 implicated in three and counting different clusters of
17 illnesses linked to their products? It's not a misuse of the
18 statute. In fact, it's exactly what Congress intended and it's
19 exactly why the bail statute exists.

20 Congress provided this remedy to the Government and the
21 public, and it would have been easy for these Defendants not to
22 get themselves subjected to conditions of release. They could
23 have not committed federal crimes, they could have not been
24 indicted twice, they could have made sure that their
25 supplements were actually safe before they put them out, and

1 the Bail Reform Act's conditions of release wouldn't be a
2 problem for them.

3 Now, the extraordinary amount of money -- and SK Labs, by
4 our calculations, made something like \$89 million during its
5 relationship with USPlabs up until 2013 -- the extraordinary
6 amount of money that they made selling these illegal products
7 has allowed them to construct a cocoon of high-priced lawyers
8 and experts who tell them what they want to hear. That's their
9 right, of course, but it's my obligation to bring a little
10 reality into this mix.

11 They have been able to avoid having a single trial in any
12 of the dozens of civil cases against them for the injuries that
13 their products caused mostly by arguing that those cases should
14 be stayed pending this one. Now, that's the only thing they
15 can do. They can't bear actually putting this evidence in
16 front of a fact finder and putting the victim in front of a
17 fact finder and having the fact finder decide whether their
18 substances actually were dangerous. The fear that somebody
19 will see through this nonsense is actually palpable. It would
20 be like a defendant who was caught with bags of white powder
21 who had been caught with bags of white power before coming in
22 here and saying the Government hadn't proven by clear and
23 convincing evidence that the powder had hurt anyone, despite
24 the fact that it seems to be showing up with people who, you
25 know, had serious injuries.

1 It's the exact same case except it's even more galling
2 because it's trading in the same stock that they've traded in
3 for eight years. They're the ones who chose to put untested
4 substances in the market that had never been fed to the public
5 before in the quantities that they had fed them to -- that they
6 put them in the products. And after they did that and after
7 people got hurt, it's time not to actually figure out what
8 happened but it's time to instead spend the millions of dollars
9 that they made selling those products attacking the people who
10 dare question them.

11 Now, SK Labs, which has no Fifth Amendment right to remain
12 silent in this context, has refused to explain why it still
13 employs a vice-president who faces literally decades in prison
14 in two different felony cases for distributing illegal,
15 dangerous substances using fraud. The reason it hasn't sought
16 to explain that is, when you read the conduct that SK Labs has
17 been involved in, when you read the emails that are quoted in
18 these indictments and that I've attached to the motion that I
19 filed, there's no excuse. There's no excuse for lying and
20 cheating and selling products that hurt people. And the emails
21 are as clear as day. It's wink-wink. It's nod-nod. It's LOL.
22 It's, oh, we'll just sell whatever.

23 And remarkably, if that weren't enough, SK Labs did it
24 three separate times. And yet they haven't told you about a
25 single product they're making now or whether the manufacturers

1 that they make those products for now have received any adverse
2 event reports for those products or anything else.

3 THE COURT: Let me focus you in on why we're here
4 today.

5 MR. RUNKLE: Sure.

6 THE COURT: We're here today because you're alleging
7 that there's a violation of his pretrial release in the sense
8 that he's got this new indictment pending. That's why I set
9 this hearing, --

10 MR. RUNKLE: Uh-huh.

11 THE COURT: -- because I was concerned, if he was
12 involved in the same sort of activity on the underlying
13 charges, that he would be subject to revocation of his release
14 or additional conditions being imposed if he was out committing
15 the same sort of offenses.

16 MR. RUNKLE: Uh-huh.

17 THE COURT: But in the responses, I see that the
18 offenses that he's charged with in the other district are
19 offenses that occurred in the same time frame as the underlying
20 indictment and nothing new since I've had him on release. Can
21 you address that?

22 MR. RUNKLE: Well, I certainly can address that.
23 First of all, I think that what we've asked for here is not a
24 revocation of his release. What we've asked for is an
25 additional reasonable condition, given the fact that there are

1 -- that there was this additional indictment that now reveals
2 that the same conduct that he committed in this case he
3 committed in other cases. And in fact, --

4 THE COURT: In the same time frame, right?

5 MR. RUNKLE: Well, --

6 THE COURT: Why didn't you ask for the revocation of
7 his pharmaceutical license and these other conditions at the
8 original time of the hearings?

9 MR. RUNKLE: Well, I'm getting there. The answer to
10 that question is, first of all, it wasn't an indicted case at
11 that time. I was generally aware of the fact that there was
12 another investigation but I wasn't aware of the specific
13 conduct. In addition, I didn't think it was my place to come
14 in here and talk about a grand jury investigation occurring in
15 another district that hadn't yet led to an indictment. That's
16 the first problem.

17 The second reason that that's -- that I didn't ask for
18 additional conditions at the time was because we didn't believe
19 that SK Labs and USPlabs' ongoing operations would present
20 really substantial issue at that time. The reason was, as Your
21 Honor may recall, there was a representation made to this Court
22 prior to Mr. Patel appearing for his initial appearance, I
23 believe, that USPlabs was winding down its business or was
24 going to wind down its business. At that time, at least,
25 USPlabs accounted for 70 to 80 percent of SK Labs' business,

1 and so the two are sort of tied at the hip. Frankly, I just
2 didn't believe that the Defendants could continue operations,
3 given the indictment and given the representations that they
4 made to this Court, but they have. And in fact, USPlabs never
5 intended to wind down its business because they were releasing
6 new products almost immediately after the indictment.

7 Now, the last reason is actually the most important. The
8 last reason that I didn't ask for those conditions is that I
9 didn't learn until a few weeks ago that -- and because that
10 indictment doesn't actually charge it, but in that case there
11 are severe injuries that resulted from those products being
12 distributed. It's not an element of the crime because the
13 products were illegal in any -- you know, coming and going,
14 they're illegal, and because they were misrepresented as
15 dietary supplements when they aren't. But in that case, when I
16 started digging into the record of that case, it turns out that
17 there's a company in Virginia called Competitive Edge Labs
18 that's Sitesh Patel conspired with in a variety of different
19 ways to sell these prohormone substances. That company chose
20 to bankrupt itself to pay settlements to all the people who
21 were injured by its products.

22 So the concept that there were no injuries from that case,
23 I -- what I knew about that case, I didn't know there were any
24 injuries. The FDA has --

25 THE COURT: But don't you allege injuries on the

1 USPlabs case?

2 MR. RUNKLE: Yes. There are injuries alleged in the
3 USPlabs case.

4 THE COURT: Similar?

5 MR. RUNKLE: It's similar. It's a very similar
6 product.

7 THE COURT: Right. So we knew that at the time I set
8 his original conditions of release.

9 MR. RUNKLE: Right, but what we didn't -- there's
10 another -- there's one more, there's one more factor to
11 consider. In this case, there was a procedure employed because
12 of the Ninth Circuit's search warrant procedures where we
13 weren't permitted to look through the SK Labs search warrant
14 materials for evidence of other crimes. We had to do a
15 relevance review at the beginning to see whether, you know, to
16 see whether the conduct fell within the scope of our search
17 warrant. That's a procedure that the Central District of
18 California employed. So there was no way for us to understand
19 the scope of that conduct or to look into the dangerousness of
20 the other conduct.

21 We understand that the aegeline -- that the, I'm sorry,
22 that the DMAA product is no longer on the market, that the new
23 OxyElite Pro product that hurt people also is not on the market
24 right now. But as you'll see, even, we have witnesses to
25 present today. You'll see that there is a cognizable and very

1 real danger that what the Defendants did before they will do
2 again if they remain in operation, because they haven't
3 explained to the Court how they came to use these dangerous
4 substances in the first place and they keep insisting to the
5 Court --

6 THE COURT: Shouldn't that be reserved for the trial
7 in this matter?

8 MR. RUNKLE: It will be re... that issue, you know, as
9 a factual matter, can be reserved for the trial, but we brought
10 witnesses today to allow the Court to get some context, not
11 just from paper but from actually -- to understand what -- the
12 conduct involved and how consumers were affected by this
13 conduct and whether it seems like a good idea for this conduct
14 to be continuing while they're pending trial, considering that
15 they're putting out new products.

16 Part of the way this industry operates is you have to find
17 a new product. You have to find a new substance to put in a
18 product, right? These Defendants refuse to admit that any of
19 these new substances that they went out and found actually hurt
20 anybody. The fact that they won't admit that or can't
21 recognize that shows that they won't be able to appreciate the
22 danger of any of the products that they're putting out now.
23 And there are additional complaints that have come in on the
24 current products that they're making and that they're putting
25 out now. Now, it's not at the level of the clusters of

1 injuries that we saw before, but there is a complaint that the
2 FDA received, I believe, in 2015. Two complaints about Jack3d,
3 the current version of Jack3d, caused, you know, heart
4 palpitations. Somebody collapsed while they're running. Those
5 kind of things just show that these products are not inherently
6 safe products.

7 And for the Court to say and for -- especially for the
8 Government to say, when we're prosecuting this case, oh, it's
9 okay, you can get indicted, you know, any number of times for
10 any number of conduct and we're not going to do anything about
11 that, we're not going to say that reasonable conditions of
12 release should be applied to you in terms of you should not be
13 making additional new products that go out in the market, you
14 should not be making products at all that people are going to
15 consume, given the conduct that we've seen in the past
16 indictments, that's -- that's where we are today. And so if
17 Your Honor would indulge me, I have three witnesses to put on.

18 THE COURT: Okay.

19 MR. RUNKLE: Okay.

20 MR. HALL: For the record, Your Honor, we have not
21 received any type of witness statements or *Jencks* Act material
22 with respect to this, and this is actually news to us.

23 THE COURT: Again, it's not the trial.

24 MR. RUNKLE: But *Jencks* doesn't --

25 THE COURT: We're not trying this case here.

Quinones - Direct

13

1 MR. RUNKLE: *Jencks* doesn't apply in a pretrial.

2 MR. HALL: I believe 26.2 does, though, Your Honor.

3 MR. RUNKLE: The Government calls Ms. Yamira Quinones.

4 THE COURT: Will you raise your right hand?

5 (The witness is sworn.)

6 THE COURT: Be seated, please. Would you state your
7 name for the record?

8 THE WITNESS: Y-A-M-I-R-A. Last name Q-U-I-N-O-N-E-S.
9 Yes.

10 DIRECT EXAMINATION

11 BY MR. RUNKLE:

12 Q Good morning, Ms. Quinones.

13 A Good morning.

14 Q How are you doing this morning?

15 A I'm doing well. How are you?

16 Q Good.

17 A Good.

18 Q Could you -- well, first, I'm going to ask you a few
19 questions about your background. Where are you from?

20 A I'm here from Dallas. I was born here and I've been here
21 --

22 Q Okay.

23 A -- all my life.

24 Q What's your educational background?

25 A I did graduate high school. I went to a technical school

1 for my certification for medical assistant. And I am currently
2 attending community college at Mountain View in Oak Cliff for a
3 degree in education.

4 Q Okay. Where do you work?

5 A I work for Baylor Scott & White for a pediatric center on
6 North Central Expressway.

7 Q I see you're in scrubs today.

8 A Yes.

9 Q Did you go to work?

10 A Yeah, I'm going to work after here.

11 Q Well, thanks for coming.

12 A Thank you.

13 Q Did you ever become familiar with a company called USPlabs?

14 A Yes, I did.

15 Q And how did you encounter USPlabs?

16 A I took one of their products.

17 Q When did that happen?

18 A Summer of 2013.

19 Q And where did you buy the product?

20 A I bought it at GNC in Irving Mall.

21 Q What product did you buy?

22 A The OxyElite Pro.

23 Q Why did you buy it?

24 A Because I wanted to lose weight and it had said that it was
25 a fast method to lose weight.

1 Q Okay. Did you take it?

2 A Yes, I did.

3 Q Did you take any other dietary supplements?

4 A No, I did not.

5 Q Are you a generally healthy person?

6 A Very healthy, yes.

7 Q So did something happen to you around the beginning of
8 2014?

9 A Yes. I had liver failure.

10 THE COURT: You had what failure?

11 THE WITNESS: Liver failure. In February.

12 BY MR. RUNKLE:

13 Q What happened? How did that happen?

14 A Well, I started having dark urine and feeling fatigued.

15 And I thought it was a bladder infection because I've always

16 been healthy, I never thought anything of it. And one day my

17 eyes turned yellow. They were fully blown yellow. And I ran

18 -- I was at work and I drove myself to Las Colinas Medical

19 Center and they rapidly got a sample of urine and they asked me

20 all these questions. Are you -- you know, do you use drugs?

21 Are you, you know, do you have sex with multiple partners? I'm

22 like, no, I don't -- thank you. I was like, I don't. And so

23 they did all these labs and then my LFTs were elevated. They

24 were above 2,000. And they were like, well, you know, they

25 checked --

1 MR. HALL: Your Honor, with respect, I believe this is
2 hearsay as to what these tests are.

3 THE COURT: Hearsay is admissible at these
4 proceedings. Thank you, sir.

5 THE WITNESS: So they tested me. They were like, do
6 you have sex with multiple partners? You know, do you do
7 drugs? And I'm like, no, sir, I don't. They did multiple
8 tests to check me for Hepatitis A, B, C, every type of
9 hepatitis. Everything came back negative. So, since my LFTs
10 were very elevated, I had to -- they admitted me in. It was
11 Valentine's, to be exact. I stayed there for a day. I stayed
12 there for -- until -- I was admitted Friday. I stayed -- I got
13 out on Sunday. Did all these labs. And I had told them I had
14 taken these pills. So when he came back, they did all these
15 lab results and they're like, that's what caused you to have,
16 you know, to have liver failure. Your LFTs were so elevated.

17 MR. HALL: Your Honor, with respect, I recognize
18 hearsay is admissible on this, but she hasn't identified who
19 the speaker is, she hasn't identified their qualifications. I
20 would ask that the Court -- I'd object as some lack of
21 foundation on this, but I would also object to these
22 conclusions that are being reached. Because, as Your Honor
23 understands, this is a hotly-contested issue, --

24 THE COURT: Yes.

25 MR. HALL: -- and they're introducing it through the

1 hearsay of this particular witness, without giving us notice or
2 an opportunity to address the underlying conclusions.

3 THE COURT: Thank you, sir. It's overruled. You can
4 continue.

5 BY MR. RUNKLE:

6 Q So, your doctor, what was -- do you remember his name?

7 A Dr. Fernandez.

8 Q Okay. He's --

9 A He's a GI at Las Colinas.

10 Q He's an emergency room physician at --

11 A Yes, sir, as well.

12 Q -- Las Colinas Medical Center?

13 A Yes, sir.

14 Q Okay. And he believed that OxyElite Pro caused the liver
15 failure?

16 A Yes. Definitely.

17 Q Okay. And there were no other risk factors that he could
18 identify?

19 A No other risk factors. I have no -- my family has no liver
20 issues at all whatsoever, and I never had them either.

21 Q You eventually came to file a lawsuit against USPlabs; is
22 that right?

23 A I did. Yes, sir.

24 Q And that lawsuit got stayed because they got charged with
25 crimes, right?

1 A Yes, sir, that's --

2 Q Do you think that the company that made that product that
3 hurt you should stay in business while they're pending trial
4 for the crimes they committed?

5 A Definitely not.

6 MR. HALL: Objection.

7 THE COURT: Sustained. While I appreciate your
8 opinion as to whether or not they should stay in business, but
9 it's really in the purview of the Court to make that
10 determination and not a particular witness, though I appreciate
11 that.

12 MR. RUNKLE: Can I try again, Your Honor?

13 THE COURT: You can, but it --

14 BY MR. RUNKLE:

15 Q Does it make you feel safe that that company is still out
16 there making product?

17 A Definitely not.

18 Q Thank you, Ms. Quinones.

19 A Thank you.

20 THE COURT: Cross?

21 MR. HALL: Thank you, Your Honor.

22 THE COURT: Just, before you ask a question.

23 EXAMINATION BY THE COURT

24 THE COURT: You say that -- the question was, does it
25 make you feel safe knowing that product is still out there?

1 What if they stopped making the product? Do you have any
2 problem with the company still being in business?

3 THE WITNESS: No.

4 THE COURT: Okay. Questions?

5 MR. HALL: Thank you. Actually, no questions, Your
6 Honor.

7 THE COURT: Thank you.

8 MR. RUNKLE: No questions, Your Honor.

9 THE COURT: Thank you. You may step down.

10 THE WITNESS: Thank you.

11 (The witness steps down.)

12 THE COURT: May this witness be excused to go to work?

13 MR. RUNKLE: Yes.

14 THE COURT: All right. Thank you, ma'am. Next
15 witness?

16 MR. RUNKLE: Next witness is Leanne Sparling, Your
17 Honor.

18 THE COURT: Ms. Sparling? Ms. Sparling, if you'd come
19 forward. Raise your right hand.

20 (The witness is sworn.)

21 THE COURT: Please be seated.

22 DIRECT EXAMINATION

23 BY MR. RUNKLE:

24 Q Good morning, Ms. Sparling.

25 A Good morning.

1 Q Could you state your name for the record?

2 A Leanne, L-E-A-N-N-E, Sparling, S-P-A-R-L-I-N-G.

3 Q Ms. Sparling, thanks for coming today.

4 A Thank you.

5 Q Where are you from?

6 A Roseville, California.

7 Q And could you give a little bit of your educational
8 background for the Court?

9 A Some college. In the past I've been an EMT and medical
10 assistant. I'm -- I've been a realtor for the last 17 years.

11 Q What kind of work do you do?

12 A Real estate. Buy, sell, and help buyers and sellers.

13 Q Okay. Ms. Sparling, have you ever become aware of a
14 company called USPlabs?

15 A Yes, I have.

16 Q How did you first become aware of USPlabs?

17 A My son was taking a supplement called Jack 3D. You can
18 either call it Jack3d or Jack 3D.

19 Q And when did you see him taking Jack3d?

20 A He graduated --

21 THE COURT: I'm sorry. Can you spell -- is it D-A-K?

22 THE WITNESS: I'm sorry?

23 THE COURT: How do you spell it?

24 THE WITNESS: Spell what?

25 THE COURT: Dak.

Sparling - Direct

21

1 MR. RUNKLE: Jack3d.

2 THE COURT: Did you say Dak?

3 THE WITNESS: Jack3d.

4 THE COURT: Jack3d?

5 THE WITNESS: Yeah. Jacked or Jack3d.

6 THE COURT: J-A-C?

7 THE WITNESS: J-A-C-K 3-D.

8 THE COURT: Okay. Thank you.

9 THE WITNESS: Uh-huh.

10 BY MR. RUNKLE:

11 Q You saw him taking Jack3d at your house?

12 A Yes, I did. Michael graduated from his advanced training
13 on his 22nd birthday. We brought him home. And then early in
14 that week he had gone to the store and bought some Jack3d. And
15 I was in the kitchen making dinner and he was stirring it in a
16 glass and I turned to him and asked him, I said, "What is
17 that?" And he turns around and he goes, "Mama, look at my
18 muscles." And I said, "What are you taking?" And he goes,
19 "Oh, it's Jack3D, Jack 3D." And I said, "Well, what is that?
20 Does it have steroids in it?" And he goes, "Mama, I wouldn't
21 be that stupid." He goes, "This stuff, this is, you know,
22 great. It's 100 percent natural." And I asked him where he
23 bought it and he said GNC.

24 Q What did you think at that time?

25 A I'm ashamed now, but I thought, oh, okay, that's fine.

1 Q So he was in the service?

2 A He was in the service.

3 Q He was a private?

4 A He was.

5 Q And this is around early 2011? Does that sound right to
6 you?

7 A Yes.

8 Q He went back to Fort Bliss?

9 A Yes, he did.

10 Q What happened?

11 A He went back. He was in processing. Met up with his troop
12 on June 1st. I received a phone call early in the morning that
13 I had missed on my phone. I had a -- kind of a sick feeling,
14 and so I went and checked my phone and noticed that I had
15 missed a call from Fort Bliss. There was a voicemail. And so
16 I got the voicemail and it was his captain at the time saying,
17 "Ms. Sparling, this is Captain Graham. I need you to call me
18 right away. Your son has collapsed."

19 Q And what happened after that?

20 A I thought to myself, oh, he must have, you know, maybe hurt
21 an ankle or something. And I called him. He says, "Ma'am, I
22 need you to talk to the commander of the hospital right now,
23 Dr. Adams." And he got on the phone. He says, "Ma'am, your
24 son has collapsed. He has had a heart attack." And I went,
25 "What happened?" And he said, "We're trying to figure it out."

1 And asked me if Michael took any drugs, did he drink, what was
2 he taking? And I said the only thing that I knew for sure that
3 he was taking was a supplement that he just started called Jack
4 3D. I told him to please let Michael know that I was on my
5 way, that I would get there as soon as I can. Sorry, Your
6 Honor.

7 THE COURT: It's all right. Take your time.

8 THE WITNESS: He said, "Ma'am, you don't understand
9 what I'm saying. Your son is in cardiac arrest and we're doing
10 everything we possibly can to save him." And I said, "Sir, are
11 you saying that my son is going to die?" And he says, "Ma'am,
12 you need to pray."

13 BY MR. RUNKLE:

14 Q You didn't get to see him?

15 A No, I did not.

16 Q And what did the doctors at the base think had killed him?

17 A When we went to the base, I --

18 MR. HALL: Well, objection as to question calls for
19 speculation, Your Honor.

20 THE COURT: It does.

21 BY MR. RUNKLE:

22 Q Did the doctors at the base talk to you about what killed
23 your son?

24 A Yes, they did.

25 Q What did they say?

1 MR. HALL: Lack of foundation, Your Honor. I'd like
2 to -- I mean, Exhibit K is the opinion from the district court
3 regarding this lawsuit striking the opinions, and so I would
4 object for lack of foundation as to what these doctors'
5 conclusions are.

6 THE COURT: Who did you talk to?

7 THE WITNESS: I talked to the commander of the
8 hospital, Dr. Bruce Adams.

9 THE COURT: And -- you can go ahead and answer.

10 THE WITNESS: Okay. He said that what he felt
11 happened was that the Jack3d, the Jack 3D in his system was
12 what started shutting down his system. It literally -- how I
13 took it is it was burning him from the inside out. He said
14 that it caused him to have the heart attack. See, there wasn't
15 anything that they found in his system. The only thing they
16 found in there was the Jack 3D and caffeine, that was it, which
17 was in the Jack 3D. He said that he was the healthiest-looking
18 soldier that had ever crossed his path. It affected him so
19 badly that he, from what I understand, even observed the
20 autopsy.

21 Michael was very healthy. He wanted to be healthy. He
22 wanted to be the best military soldier that he could possibly
23 be. And he thought by taking the Jack 3D that it would help
24 him become that.

25 Michael -- Your Honor, Michael was smaller than my other

Sparling - Direct

25

1 two children, and that weighed heavy on his heart, too. You
2 know, he wanted to be the bigger brother. And he just, he
3 goes, "I just want to be healthy. I want to be as fit as I
4 possibly can be." And that's why he started taking this,
5 because he believed that it was natural. He told me it was
6 natural. And I have since found out that it wasn't. It was
7 synthetic. It was man-made. It was made in a factory in
8 China. You know, this is a -- I'm sorry I'm rambling. This is
9 a chemical --

10 MR. HALL: Your Honor, objection. There's no question
11 pending.

12 THE COURT: Sustained.

13 BY MR. RUNKLE:

14 Q So, Ms. Sparling, after that happened, you filed a lawsuit
15 against USPlabs?

16 A Yes, I did.

17 Q All right. And did you contact USPlabs before filing a
18 lawsuit?

19 A No, I did not.

20 Q Did -- is it your impression that USPlabs was interested in
21 finding out what actually happened to your son?

22 MR. HALL: Well, objection as to speculation.

23 THE COURT: Sustained.

24 BY MR. RUNKLE:

25 Q What happened in the course of that lawsuit?

1 A Ultimately, it was -- they felt like I was after money, and
2 at one point offered a deal, but it was never about the money.
3 It --

4 Q What was it about?

5 A It was about what they did to my son. It was what they did
6 to so many other people that I've personally spoken with.

7 Q So you spoke to other people who had issues with this
8 product?

9 A Yes. It became a mission of mine to seek out people. And
10 people would call me and say, you know, my son or daughter has
11 taken this. You know, I had gone into a GNC and was
12 questioning the product and asked if they had known of any
13 adverse reaction, and this was -- this part was before I even
14 filed the lawsuit -- and they said, no, you know, they don't
15 know of any adverse effects. And then he goes, oh, wait a
16 minute, I do know of one. And I said, "Well, what is that?"
17 And he goes, "Well, I have heard that people have tested
18 positive for meth." And I said, "Well, that doesn't sound very
19 safe to me."

20 Q Do you have concerns about the safety of your community
21 because these people are still in operation today?

22 A Of course I do. I try to speak out to as many people as I
23 possibly can because -- and who is going to protect us, the
24 consumers? Everybody is protecting them. Everybody is
25 protecting the people that killed my son and has hurt so many

1 people.

2 Q Thank you, Ms. Sparling.

3 THE COURT: Cross?

4 CROSS-EXAMINATION

5 BY MR. HALL:

6 Q Good morning, Ms. Sparling. My name is Patrick Hall. I
7 represent Sitesh Patel. Have you ever heard that name before?

8 A Yes, I have.

9 Q You filed lawsuit in the -- on behalf of the estate of
10 Michael in the Western District of Texas, correct?

11 A Yes.

12 Q And ultimately that lawsuit was dismissed, correct?

13 A I dis... yes.

14 Q All right. And there was liti... you hired lawyers to
15 represent you and litigate that case, correct?

16 A Yes, I did.

17 Q And in that case, they tried to contact experts to reach
18 opinions regarding what caused your son's death, correct?

19 A Correct.

20 Q And ultimately the judge struck the opinions of the experts
21 in that case, concluding that that was -- that their opinions
22 were unreliable, correct?

23 A I don't know if their opinions were unreliable. They were
24 very reliable to me.

25 Q Well, you've seen the opinion of the judge, correct?

1 A Yes, I have.

2 Q Right. And the judge specifically said that the doctors'
3 conclusion that what the cause of your son's injury was was
4 Jack 3D was unreliable and he struck that judge's -- or she
5 struck that expert's opinion, correct?

6 A I think that the report that they reviewed could not say
7 whether or not for sure if it did cause his death or not. I
8 was always told by the doctors that it did contribute to his
9 death, yes, and that's what I believe.

10 Q That's what you believe. But the judge struck the opinion
11 and your suit was dismissed, correct?

12 A They dismissed it, yes. They wouldn't hear our --

13 Q For lack of causation, correct?

14 THE COURT: She doesn't know that, so ask her for --

15 MR. HALL: Okay.

16 BY MR. HALL:

17 Q You said you first -- when your son was first in the
18 hospital you spoke to Dr. Adams; is that correct?

19 A Yes, I did.

20 Q And he was the one that told you that we're trying to
21 figure out what happened, correct?

22 A Correct.

23 Q And then you later referenced speaking to a doctor at the
24 hospital about what he felt happened. Was that Dr. Adams as
25 well?

1 A It was Dr. Adams and also another doctor, and I don't
2 recall his name.

3 Q All right. And was that doctor who gave you the opinion
4 about what he felt had happened, was he involved in your civil
5 litigation at all?

6 A You'd have to ask my attorneys.

7 Q Was -- well, did you ever follow up with that particular
8 doctor again about his opinion about what he felt happened?

9 A I've been told that he's retired.

10 Q Did he tell you what his basis for his conclusions about
11 what he felt happened were?

12 A What I remember of our conversation, he had come across
13 other patients that had had adverse reactions to Jack 3D. He
14 also was telling me about rhabdomyolysis, which also happened,
15 which sent off acid throughout his body, shutting down every
16 organ. That he couldn't even be an organ donor.

17 Q Were you deposed in connection with the litigation?

18 A Yes, I was.

19 Q Now, the Judge or Mr. Runkle asked you some questions about
20 your concerns about the company. When you're talking about the
21 company, are you talking about USPlabs or are you talking about
22 SK Labs?

23 A To me, they are both the same.

24 Q Have you ever done any investigation of what SK Labs does?

25 A Just through the Internet.

1 Q You didn't file a suit against SK Labs, correct?

2 A No.

3 Q All right. And the Internet research that you have done,
4 when did that occur?

5 A As soon as I got back home from Fort Bliss, I started
6 researching everything I could to find out what happened to my
7 son.

8 Q All right. Now, --

9 A That was the promise I made to him.

10 Q All right. Now, you talked about your son taking this.
11 When was it that he started taking this?

12 A I'm going to say the first week of May. We came home April
13 30th and he started taking it that next week.

14 Q The first week of May of 2011?

15 A Yes.

16 Q All right. And do you have any knowledge about what USP is
17 currently making?

18 A No.

19 Q Do you have any knowledge about what SK Labs is currently
20 making?

21 A No.

22 MR. HALL: Nothing further of this witness, Your
23 Honor.

24 THE COURT: Thank you. Any other questions?

25 MR. RUNKLE: No further questions, Your Honor.

1 THE COURT: Thank you, Ms. Sparling.

2 THE WITNESS: Thank you.

3 (The witness steps down.)

4 THE COURT: Next witness?

5 MR. RUNKLE: Our next witness is Dr. Patty Deuster.

6 THE COURT: Dr. Patty--?

7 MR. RUNKLE: Deuster, D-E-U-S-T-E-R.

8 THE COURT: Thank you.

9 MR. RUNKLE: Your Honor, I'd like to ask if Mr. Hall
10 or if Mr. McMullen has any objection to Ms. Sparling watching
11 the remainder of the hearing.

12 THE COURT: Any objection?

13 MR. HALL: No objection, Your Honor.

14 THE COURT: Thank you.

15 MR. MCMULLEN: No objection, Your Honor.

16 MR. RUNKLE: Thank you.

17 THE COURT: Thank you. Doctor, if you'd raise your
18 right hand?

19 (The witness is sworn.)

20 THE COURT: Be seated, please.

21 DIRECT EXAMINATION

22 BY MR. RUNKLE:

23 Q Good morning.

24 A Good morning.

25 Q If you could state and spell your full name for the record,

1 please.

2 A Spell every -- Patricia Ann Deuster, D-E-U-S-T-E-R.

3 Q Dr. Deuster, could you give us a bit of an educational
4 history and work history for yourself?

5 A Educational history, I got my first degree in mathematics,
6 my second degree in education, physical education, my PhD was
7 in nutritional biochemistry and physiology, and I have a
8 master's in public health.

9 Q And you've worked somewhere since 1982. Where is that?

10 A I have. I've worked at the Uniformed Services University
11 of the Health Sciences, which is the federal health sciences
12 university. We have a school of medicine, a graduate school of
13 nursing, and a post-graduate dental school.

14 Q What are your current titles?

15 A I am a professor in the Department of Military and
16 Emergency Medicine, and I have been there since, as you said,
17 1982. I'm also the chair of the Department of Defense Dietary
18 Supplements Sub-Committee, and I'm also the director of the
19 Consortium for Health and Military Performance, which is the
20 Defense Center of Excellence for Health and Performance within
21 the Department of Defense.

22 Q So your job is to keep soldiers healthy, right?

23 A That's correct.

24 Q That's you --

25 A Well, soldiers, sailors, airmen, and marines.

1 Q And that's what you do every day?

2 A That's what I do every day.

3 Q So in your job as chair of the Dietary Supplement -- I
4 forget the full name.

5 A Dietary Supplement Sub-Committee. It's actually the
6 Dietary Supplement and Other Self-Care Products Sub-Committee.

7 Q Okay. The Dietary Supplement and Other Self-Care Products
8 Sub-Committee. How long have you had -- have you been in that
9 committee?

10 A I have been on that committee for about 20 years. It
11 wasn't formally chartered until about eight or nine years ago,
12 and I have the chair of that since then.

13 Q Now, before we get to the specific products that are at
14 issue right here, could you talk generally about dietary
15 supplements and the military?

16 A Well, one of our jobs in the military is to find
17 supplements that are safe and could actually enhance
18 performance. That's one of -- also, we are supposed to be
19 looking at ones that could potentially cause harm and
20 compromise readiness. We need them to be able to perform on a
21 dime in very adverse environmental conditions and be ready.

22 Q Do service members take a lot of dietary supplements?
23 Generally?

24 A Actually, generally, they take more than the civilian
25 population. They may be for health, but a lot of them are

1 bodybuilding, weight loss, and performance-enhancing.

2 Q Have you ever become aware of a company called USPlabs?

3 A Yes. I became aware of that company a number of years ago,
4 yes.

5 Q How did you become aware of it?

6 A I first became aware of it when a colleague of mine has a
7 son who was in college and he wrote back that he was taking a
8 product called Jack 3D or Jack3d and it made him feel really
9 strange. And so we got the label and we looked it and I
10 realized that it said USPlabs, which was a concern for me
11 because I know about United States Pharmacopeia, which is also
12 USP.

13 Q Uh-huh. And why were you concerned about the product other
14 than the name?

15 A Because I looked -- we looked at the ingredients. It had a
16 number of ingredients that were not terribly familiar to me at
17 the time, and it had a combination of ingredients, and we're
18 always concerned when there are multiple ingredients in a
19 dietary supplement.

20 Q And one of those ingredients purported to be from
21 geraniums, right?

22 A Well, it said dimethylamylamine, DMAA, from geranium
23 extract, yes, or geranium leaves. Yes.

24 Q Okay. And was it from geraniums?

25 A I don't think it was from geranium. I did a literature

1 search and did some background work and found that it had
2 actually been a drug in the 1940s, '50s, called Forthane, and
3 it was for a nasal decongestant. There were a number of
4 studies in the literature.

5 Q And you found something about a guy named Patrick Arnold?

6 A Yes, I found on the Internet that in -- it was in 2005 that
7 Patrick Arnold -- actually, it was Proviant Technologies --
8 wanted to order anywhere from 5 to 25 kgs per month of DMAA.
9 And it didn't say anything about geranium. It just said DMAA.
10 And it had a list of all the different articles and so on that
11 had been conducted.

12 Q Okay. When did you encounter -- and Patrick Arnold is
13 famous --

14 A From the BALCO.

15 Q BALCO.

16 A Yes.

17 Q (inaudible)

18 A Designer steroids, yes.

19 Q So when did you encounter USPlabs again?

20 A Well, we started seeing lots of different products from
21 USPlabs, but I suppose my next real encounter was when I got a
22 call -- I heard from the military, from the Army, that there
23 had been a death and it was that the young soldier had been
24 taking dimethylamylamine. I was contacted by the attending
25 physician, and as chair of the Dietary Supplement Sub-

1 Committee, and also because we had an adverse event working
2 group where we were trying to help people or encourage more
3 physicians and healthcare providers to report adverse events,
4 they contacted me and asked me if I would contact the mother,
5 and that was Leanne Sparling.

6 Q And did you talk to Dr. Adams?

7 A Oh, I spoke with him a number of times. We exchanged
8 emails. Absolutely.

9 Q Did any member of your team think that anything other than
10 Jack3d caused this death?

11 A No.

12 Q Were there adverse event reports with Jack3d and OxyElite
13 Pro?

14 A Yes, there were a number of them. There were a number that
15 we got from the Marines, from the different services, and there
16 was also then another death a couple of months later, the same
17 base, from a woman who was taking OxyElite Pro and some other
18 supplements.

19 THE COURT: What was she taking?

20 THE WITNESS: OxyElite Pro.

21 BY MR. RUNKLE:

22 Q And that's one of USPlabs' products?

23 A That was a USPlabs product as well, yes.

24 Q Now, eventually, the military pulled those products from
25 the GNC concessions?

1 A That's correct.

2 Q And you were part of that decision?

3 A I was. Well, I asked for them to do that. They did not
4 follow my lead but they eventually came off.

5 Q Now, there was a safety review commission, a safety review
6 panel that was commissioned?

7 A Correct.

8 Q You were part of that?

9 A I was.

10 Q Okay. Now, the Defendants in this case have said that that
11 safety review panel concluded that the deaths were not caused
12 by DMAA. Is that what the panel concluded?

13 A I'm guess in a sense they did because it's almost
14 impossible to prove causation, because to get the highest
15 evidence of causation, one, you're supposed to re-challenge.
16 You're supposed to take the person off the supplement and then
17 re-challenge them, and that's really very difficult to do if
18 the person is deceased. So I think there's a problem with the
19 science.

20 Q Okay. But your conclusion was not that it was impossible
21 that DMAA caused this?

22 A Oh, no. I thought it was very likely that it had.

23 Q Okay. And your -- the panel made other findings; is that
24 right?

25 A Yes.

1 Q One of those findings was that people who took DMAA were
2 more likely to have multiple adverse events; is that right?

3 A That's correct.

4 Q Do you stand by that finding?

5 A Absolutely.

6 Q All right. In your time on that panel -- how many members
7 of that panel were there?

8 A Well, there was a group of about 15 of us who met on a
9 regular basis, and then the group at the United States Army
10 Public Health Command at the time, now Center, actually did the
11 epidemiologic work on this study.

12 Q When you talked to all of those people and, you know, when
13 you look back on this experience, did any of those people in
14 your mind believe that DMAA was safe?

15 MR. HALL: Objection, Your Honor, as to ambiguous as
16 to what "in your mind" means.

17 THE COURT: I'll allow it.

18 THE WITNESS: I think that there were some people who
19 had no knowledge of dietary supplements, and I think that's a
20 general issue throughout the United States. People don't
21 really understand dietary supplements. So they didn't know
22 what DMAA was and so they didn't know whether it was safe or
23 not. At the end of all of the investigation, they were
24 concerned that it should not be in dietary supplements.

25 BY MR. RUNKLE:

1 Q And has there been other research that you've become aware
2 of about the addiction potential of DMAA?

3 A There was a paper that came out that showed that it could
4 be addictive, yes.

5 Q In fact, that paper said that it had 100 percent,
6 potentially, of the addictive capability of cocaine?

7 A That's correct. Now, of course, that's very difficult --
8 those studies are very difficult to do, but those were the
9 conclusions, yes.

10 Q But you weren't done on the USPlabs rollercoaster yet at
11 that time, were you?

12 A No.

13 Q What happened next?

14 A Well, after -- they took OxyElite Pro off, and then they --
15 they have had another one that came on the market. It was the
16 second version. And then the third version was with aegeline,
17 and there were a number of liver injuries, and so I
18 participated in that as a member of the Department of Defense
19 with CDC and FDA on that panel as well.

20 Q That was much more recent, right?

21 A That was much more recent, yes.

22 Q And there were service members who were injured by that
23 product?

24 A There were a number of service members. I don't have the
25 exact count, but it was anywhere from 20 to 30 to 40, something

1 like that, yes.

2 Q And in your 30 years of experience working on these issues,
3 could that cluster of injuries have been caused by anything
4 else?

5 A Not in my mind, no.

6 Q So what I want to ask you about are untested supplements
7 being put in dietary supplements, right? Is it possible for a
8 company to put an untested substance in a dietary supplement in
9 the United States?

10 A Absolutely.

11 Q It happens all the time?

12 A It happens all the time.

13 Q And in fact, the supplement world runs on, hey, this is a
14 new substance that's going to help you, right?

15 A That's correct.

16 Q All right. And so there's nothing preventing a company
17 from saying, hey, we're going to try this substance and see
18 what works, right?

19 A That's correct.

20 Q And what you see is a serial -- a series of events where
21 certain substances become more popular, certain -- I'm sorry.
22 Scratch that. What you've seen is certain substances that you
23 would consider risky substances having spikes of popularity.
24 Is that right?

25 A That's correct. But we also have tested lots of products

1 and we find steroids, stimulants, lots of different stimulants,
2 and actually drugs in the -- when we do the testing.

3 Q Right. Are you familiar with prohormones?

4 A I am.

5 Q Okay. What are prohormones?

6 A A prohormone is a substance that is metabolized into
7 usually, for us, anabolic steroid or testosterone. So it would
8 be a testosterone analog.

9 Q And Congress explicitly banned those what I'll call
10 designer prohormones at some point; right?

11 A That's correct. In 2014 was the Designer Steroid Control
12 Act, yes.

13 Q But those substances weren't necessarily legal or safe
14 before then, were they?

15 A They were never safe, and it's questionable whether they
16 were legal. They're not really legal. They're just not
17 necessarily deemed illegal because they haven't been
18 identified.

19 Q And in your job today, are you monitoring new trends of
20 different types of substances that are now making their way to
21 the market?

22 A We do our very best to monitor. It's difficult to keep up
23 with all of it, but we are doing our very best to keep our
24 service members safe.

25 Q Now, you understand that a company in California called SK

1 Labs produced those products that we talked about earlier?

2 A Yes, I understand that that's the case.

3 Q Okay. Are you concerned about the safety of service
4 members that that company is still in operation while it's
5 pending trial?

6 A I'm very concerned about it. Because, again, my job is to
7 try to keep our service members safe and ready for their jobs,
8 and that compromises readiness and the health and safety of our
9 service members.

10 Q Because there would be nothing preventing them from finding
11 some new substance, hurting more people, and saying, hey, we
12 didn't know that it was going to hurt anybody, right?

13 A No, and they don't know that it's going to hurt them
14 because they aren't knowledgeable enough, and they hear from
15 their buddies that this works. And it's a problem. It's a
16 serious problem.

17 Q Thank you, Dr. Deuster.

18 THE COURT: Cross?

19 MR. HALL: Thank you.

20 CROSS-EXAMINATION

21 BY MR. HALL:

22 Q Good morning, Doctor.

23 A Good morning.

24 Q Let me start with your investigation regarding Michael
25 Sparling. Were you summoned as an expert to testify in that

1 case?

2 A I was not allowed to testify as a federal employee.

3 Q And you are aware of ultimately what happened in connection
4 with that litigation?

5 A I am.

6 Q And you're aware that the judge struck the opinions that
7 had been proffered by the Plaintiff's counsel as unreliable and
8 lacking in proper foundation and scientific method?

9 A That's my understanding.

10 Q And have you studied the opinions that those doctors and
11 those experts rendered in that case?

12 A I think they had the wrong experts, is my professional
13 opinion. There are a number of people who could have testified
14 that may have changed the outcome.

15 Q So does that mean that you looked at the opinions that were
16 rendered by the doctors?

17 A I've looked at a couple of them. I have not spent a lot of
18 time doing that, no, sir.

19 Q You talked about you're familiar with the products that SK
20 Labs has manufactured. What specifically products are you
21 talking about?

22 A I think we're talking more about ingredients than we are
23 talking about products.

24 Q All right. But Mr. Runkle asked you if you're familiar
25 with the products that SK manufactures. Are you familiar with

1 the products they manufacture?

2 A No. I think I -- I thought he had asked about ingredients.
3 People get --

4 THE COURT: Doctor, I think the real question is, do
5 you know of any product that they are now producing that is
6 harmful to any service person?

7 THE WITNESS: I can't say, yes, there is a particular
8 product right this minute. I know there are a number of
9 products out there that I am concerned about. Can I name them?
10 No, because I have staff that help -- that keep up with all of
11 that.

12 BY MR. HALL:

13 Q What about if -- what would your thoughts be if -- I mean,
14 you have concerns about -- is it your position that, as Mr.
15 Runkle's position is, that SK Labs should be closed down today?

16 A I would say absolutely yes, given what's happened in the
17 past.

18 Q What about if there was some type of monitor in position
19 that could verify the ingredients that were going into all of
20 their products? Would you have the same concerns?

21 A Well, I think that the companies that use third-party
22 certification verification, you usually know exactly what's in
23 the product and that the label -- what's stated on the label is
24 in the product. I don't think that's true of most of the
25 products, because we've analyzed a number of the ones from

1 USPlabs.

2 Q So your -- part of your conclusion, though, is based on a
3 presumption that SK Labs does not do independent testing of the
4 ingredients?

5 A Not by a recognized body like NSF International or USP.

6 Q What about WADA?

7 A WADA is not a third-party certifier.

8 Q But you do understand that they need to be -- have to be
9 screened by WADA to be a member and they have a list of
10 products and ingredients that can be included in products,
11 right?

12 A I'm well aware of WADA, but, again, it is not a recog... it
13 is not a third-party certifier or verifier like the NSF,
14 Informed-Choice. There's the Banned Substances Control Group.
15 They actually verify supplements.

16 Q All right. So I guess my question goes back to, if there
17 was something in place at SK Labs where all of the ingredients
18 were independently tested or verified as to what their contents
19 were, would that make you -- would you still have the concerns
20 with SK Labs?

21 A I would, based on history.

22 Q Thank you very much.

23 MR. RUNKLE: I have nothing further, Your Honor.

24 THE COURT: Thank you, Doctor. You're -- can this
25 witness be excused?

1 MR. RUNKLE: This witness may be excused.

2 (The witness steps down.)

3 MR. RUNKLE: Your Honor, does Mr. Hall or Mr. McMullen
4 have any objection to Dr. Deuster staying for the rest of the
5 hearing?

6 THE COURT: Yes.

7 MR. HALL: No objection, Your Honor.

8 MR. RUNKLE: Thank you.

9 THE COURT: What else for the Government?

10 MR. RUNKLE: Your Honor, I just have a few -- I have a
11 few additional items. I wanted to respond to some of the legal
12 points that were made in the responses, if Your Honor will
13 indulge me on that. I have a presentation that I made up. I
14 thought it would be easier than filing another brief. Enough
15 trees have been sacrificed already here.

16 On the legal issues, the Bail Reform Act does not require a
17 clear and convincing showing to set standard conditions of
18 release. The Court does this every day. The Act requires a
19 clear and convincing showing only under Subsection F because it
20 reads, "The facts a judicial officer uses to support a finding
21 pursuant to Subsection E that no condition or combination of
22 conditions will reasonably assure the safety of any other
23 person and the community shall be supported by clear and
24 convincing evidence." Subsection -- that's an explicit
25 reference to Subsection E, which is about detaining the person.

1 We haven't asked for him to be retained.

2 The next legal issue, the Bail Reform Act gives the Court
3 discretion to -- at any time to impose additional or different
4 conditions of release. We've talked about this already.

5 I also would implore the Court to consider the public
6 interest in the fact that someone who has been indicted twice
7 for this type of behavior is being allowed unfettered business
8 activity in the same realm.

9 The next legal issue that the Defendants raised was whether
10 the Bail Reform Act could apply to a corporation. SK Labs is,
11 I think we all agree, is a person charged with an offense. If
12 it can be charged with an offense, it can have conditions of
13 release, because the U.S. Code presumes that business entities
14 are people unless Congress's intent would not be served by the
15 presumption. The fact that there are certain conditions in the
16 Bail Reform Act that could only be applied to people doesn't
17 make the other conditions that could be applied to corporations
18 not applicable to corporations.

19 The other argument that I make here that I would like the
20 Court to consider is that when Congress wrote a companion
21 statute about DNA sample collection, it used the word
22 individual when it was talking about a person but it didn't
23 change the language about companies.

24 And I just have a few more factual issues that have come up
25 from the responses, and I would like to present the Court with

1 just several small pieces of evidence and then I will sit down.

2 The Defendants in their responses make a representation
3 that Mr. Patel has not been involved in distributing
4 prohormones since 2011. The text message that we found on Mr.
5 Patel's phone from August 6, 2013, Mr. Patel texted a shipper
6 named Neil Corbin who does work both for USPlabs and SK Labs,
7 and the text message reads, "Crap, got caught --

8 MR. HALL: I'm going to enter an objection on this,
9 Your Honor. This is the first time I've seen this. But
10 certainly I've got questions regarding what the basis for this,
11 what the foundation is, and he's representing that it's on his
12 cell phone, and I have no verification or idea if that's
13 accurate or correct. And so I certainly object to this.

14 THE COURT: Thank you. The objection is overruled.

15 MR. RUNKLE: All right. Mr. Hall has -- the text
16 message reads, "Crap, got caught on that fake pro shipment."
17 And I have another document establishing that Mr. Corbin is
18 involved in shipping. Is it Exhibit 3 -- this document just
19 establishes Mr. Corbin's role, which is to ship products back
20 and forth between USPlabs and SK Labs. I'm offering this as an
21 attorney proffer, but I don't know what, "Crap, got caught on
22 that fake pro shipment" exactly means, but I believe that "pro"
23 means prohormones and fake is the type of conduct that he was
24 just charged with in the Western District of Virginia where he
25 was making fake shipments where the good stuff would be on the

1 top and the illegal stuff would be on the bottom. So the idea
2 that he's not involved in these activities today seems remote.

3 THE COURT: Well, this was in 2013, and my
4 understanding was they made -- Congress passed a law that these
5 prohormones were illegal in 2014.

6 MR. RUNKLE: Right. Well, what he -- but the
7 substances were illegal under the Food, Drug, & Cosmetic Act
8 prior to that, right?

9 THE COURT: I understand that, but this is still three
10 years ago.

11 MR. RUNKLE: It is still three years ago, Your Honor.

12 And for the question that the Court has asked several times
13 now, I will tell the Court that there have been complaints
14 about USPlabs' products that have been received on MedWatch
15 reports within the last year or two.

16 THE COURT: Of products that are currently being
17 manufactured?

18 MR. RUNKLE: Yes.

19 THE COURT: Okay.

20 MR. RUNKLE: And as I said, I can --

21 THE COURT: And tell me about these products.

22 MR. RUNKLE: I will.

23 THE COURT: What products?

24 MR. RUNKLE: The product is the current version of
25 Jack3d.

1 THE COURT: What's it called?

2 MR. RUNKLE: One moment, Your Honor. I'm sorry.

3 THE COURT: And this is SK or USP?

4 MR. RUNKLE: This is -- it is a USPlabs product. We
5 believe that Jack3d is made at SK Labs.

6 THE COURT: Okay.

7 MR. RUNKLE: It certainly was made at SK Labs, and Mr.
8 Patel was the originator of the Jack3d formula.

9 The products -- (pause). I apologize, Your Honor. I need
10 one moment to find this information.

11 (Pause.)

12 MR. RUNKLE: There's a complaint about Jack3d on
13 November 29, 2015 that came into the MedWatch system on March
14 8, 2016. The --

15 THE COURT: But the complaint was in November of 2015;
16 is that correct?

17 MR. RUNKLE: That complaint. Yes, the actual health
18 episode occurred then. It's the same type of complaint that
19 has happened --

20 THE COURT: And do we know if this Jack3d was produced
21 -- when it was produced?

22 MR. RUNKLE: It would have been produced, my
23 understanding is that it has about a -- well, I wouldn't be
24 able to tell you exactly when it was produced.

25 THE COURT: No, because we don't know if this was Jack

1 3D that he bought from someone or from anywhere else. So, --

2 MR. RUNKLE: Well, Jack3d comes from SK Labs, Your
3 Honor.

4 THE COURT: I understand, --

5 MR. RUNKLE: Oh, okay.

6 THE COURT: -- but it could have been an old product
7 that they stopped manufacturing.

8 MR. RUNKLE: Well, they're still manufacturing Jack3d
9 today.

10 THE COURT: Right. And what's in Jack3d now that
11 they're manufacturing that you have concerns about?

12 MR. RUNKLE: Well, there's a -- it's a -- there's a
13 large amount of caffeine. There is a substance called arginine
14 nitrate.

15 THE COURT: That you can find the same thing in No-
16 Doz. Is that on the market?

17 MR. RUNKLE: I know. No, there's a substance, I
18 believe, called arginine nitrate, and the defense counsel can
19 correct me if arginine nitrate is still in Jack3d as we speak.
20 There are a number of formulations, which is part of the
21 problem, is that the defense is -- Defendants are moving
22 targets.

23 Arginine nitrate has been associated, from my knowledge,
24 with brain bleeds that have occurred in some consumers. And
25 arginine nitrate is not a dietary ingredient that is able to be

1 put in dietary supplements. It's a -- it's not an amino acid.
2 It is not a -- it's not one of the substances in the list in
3 the Food, Drug, & Cosmetic Act that are the subject --

4 THE COURT: So, I'm sorry to interrupt you again, --

5 MR. RUNKLE: Yes.

6 THE COURT: -- but tell me, is this amino -- or
7 arginine nitrate --

8 MR. RUNKLE: Arginine nitrate.

9 THE COURT: -- arginine nitrates currently being
10 placed in the manufacture of Jack3d?

11 MR. RUNKLE: Well, arginine nitrate was in Jack3d as
12 late as last year, I believe.

13 THE COURT: All right. Currently, is there -- is it
14 in Jack3d now?

15 MR. RUNKLE: I do not know.

16 THE COURT: Okay.

17 MR. RUNKLE: As Dr. Deuster said, the concern is that
18 --

19 THE COURT: The formula.

20 MR. RUNKLE: -- the formulas change all the time.

21 THE COURT: Right.

22 MR. RUNKLE: Right. And we have no idea what will be
23 in Jack3d tomorrow.

24 That's all I have, Your Honor. Thank you very much for
25 your indulgence.

1 THE COURT: Well, tell me what remedy you're asking
2 the Court to impose.

3 MR. RUNKLE: Okay. The first remedy is, given the
4 fraud that's in the Sitesh Patel emails that are in the
5 indictments and that I've attached to the motion, we don't
6 believe Sitesh Patel should be in business in the FDA business.
7 There's too much fraud there. There's too much of a history
8 there. And it seems to be a very reasonable condition of
9 release for Mr. Patel to avoid the type of conduct that he's
10 been involved in in the past, which is defrauding consumers
11 with dietary supplements that certainly appear that they may be
12 harmful.

13 And I'm not asking the Court to make a factual finding that
14 the products were harmful. I'm asking the Court to consider
15 the evidence about Mr. Patel.

16 As to SK Labs, there is -- although I think that SK Labs
17 should be shuttered, given its history, a possible alternative
18 remedy would be to order SK Labs to stop doing business with
19 companies of people who have either been convicted of Food,
20 Drug, & Cosmetic Act crimes or are pending trial on Food, Drug,
21 & Cosmetic Act crimes.

22 THE COURT: You mean SPLabs. USPlabs.

23 MR. RUNKLE: Or anybody else. As the Defendants
24 pointed out, there is a guy named Jared Wheat who is running
25 around selling DMAA or attempting to sell DMAA products and

1 also has prior FDCA convictions. There are a lot of people in
2 the world who have convictions for doing this type of thing,
3 and it seems like a very reasonable condition of release to
4 order SK Labs to stop doing business with those companies. I
5 mean, the -- Mr. Geissler has a prior controlled substances
6 conviction in the state of Texas also. That seems like a very
7 reasonable condition of release that would be applied -- could
8 be applied to any defendant. So that would be my alternative
9 request, Your Honor.

10 THE COURT: How can we stop them from just changing
11 their corporate name and doing business with someone that's not
12 under indictment, --

13 MR. RUNKLE: Well, we can --

14 THE COURT: -- doing the same thing?

15 MR. RUNKLE: Well, we can write the order to cover
16 their --

17 THE COURT: Well, it's almost like thought police
18 here.

19 MR. RUNKLE: No, I don't think it's thought police. I
20 think that there's a -- they stop doing business with companies
21 or people who are either pending trial for or have been
22 convicted of Food, Drug, & Cosmetic Act related crimes.

23 THE COURT: Got you. Can you delineate those
24 companies that they're doing business with that are currently
25 under indictment or have been convicted of crimes?

1 MR. RUNKLE: Well, there's -- they've done business
2 with --

3 THE COURT: We know USPlabs.

4 MR. RUNKLE: Yes, USPlabs. Willie Gomez seemed to be
5 a favorite of Sitesh Patel. Willie Gomez is now under
6 indictment in the Western District of Virginia. And if the
7 Court orders SK Labs to provide us with a list of their
8 clientele, we can do research and determine which ones of them
9 have been convicted or are pending trial for Food, Drug, &
10 Cosmetic Act related crimes.

11 THE COURT: Okay. Thank you.

12 MR. RUNKLE: Thank you, Your Honor.

13 THE COURT: For the Defense?

14 MR. HALL: Thank you, Your Honor. On behalf of Mr.
15 Patel, let me start with kind of reverse order here. The
16 product, the Jack3d product that is referenced in this November
17 29, 2015 complaint, if it contains arginine nitrate, it was not
18 manufactured at SK Labs. That is something that USP uses
19 multiple manufacturers, I believe, at this point in time for
20 Jack3d, and if it contains that, that's not something that came
21 within the past three, four, five years from SK Labs.

22 THE COURT: Okay.

23 MR. HALL: The current version of Jack3d contains
24 caffeine, an entirely legal product, but not this arginine
25 nitrate.

1 Your Honor, I have a whole bunch of comments here --

2 THE COURT: Okay.

3 MR. HALL: -- about the Government's case, but I would
4 prefer to cut to the chase and get to the very bottom of what
5 the Court's concerns are, and start out with Mr. Patel is very
6 serious about this case. The inferences that have been drawn
7 by Mr. Runkle from his lack of apparent communication with the
8 prosecutors is he's -- you know, there are certainly some
9 hotly-contested issues in this case, including causation, as
10 claimed by this doctor for whom I had no notice of, all right,
11 and I certainly didn't do a great job of cross-examining her
12 regarding her tests and foundations, but we don't have any of
13 that expert evidence before me.

14 But today what I want to do is propose to the Court
15 something that assures the Court that Sitiesh Patel is not out
16 there violating the law and is not committing ongoing crimes.
17 And we started with and we emphasize that there was a current
18 audit done. Mr. Lassiter and his assistant, Mr. Guo
19 (phonetic), who performed that audit, are both present in court
20 today to talk about that, if the Court has questions about that
21 particular audit. But this isn't the first time that they've
22 been audited. This is actually the second audit. So, before
23 any of these allegations, you know, any of these indictments
24 occurred, SK was concerned about their manufacturing processes
25 and had engaged them back in 2015 to do a similar type of study

1 to assure it.

2 The most recent study that you have before Your Honor as
3 Exhibit D in our pleadings is actually the study that was
4 requested and the evaluation requested by us to assure the
5 Court that they're not currently violating the law or
6 distributing products that are a danger to the community.

7 We hotly contest the issue of danger to the community. Ms.
8 Sparling testified today, but there really is no causation link
9 there, and the judge thoughtfully and, after reviewing lengthy
10 depositions of the experts and cross-examination, came to the
11 conclusion that that -- that there was unreliable opinion. And
12 Dr. Deuster, if I have her name correct, concludes that maybe
13 they used the wrong experts. But in this instance, Your Honor,
14 the evidence in that case is that there was no causation.

15 We would -- I'd like to emphasize a couple of things about
16 this indictment in the Western District of Virginia. And when
17 Your Honor asked the question, I think you hit it on the head,
18 is that when you first read this motion it looks like Mr. Patel
19 is out there committing violations while he's on bond in this
20 case, and that's a -- a rebuttable presumption arises at that
21 point in time, I believe, under the Act. This is not the case.
22 This is, in fact, conduct that precedes, really, what's at
23 issue here in this USP, what I call the USP indictment.

24 And so it's older conduct, and we're not taking it lightly
25 and he's not taking it lightly. And so what we want to do is

1 satisfy the Court that he doesn't lose his career that he came
2 out.

3 So, as Your Honor has read, I'm sure, he left Rutgers and
4 began working for his father, and in the first three years was
5 involved in this industry after he got his doctorate in
6 pharmacy. Almost all of the emails that the Government has
7 referenced involve those first three years, although I'm seeing
8 something today, a text message, which we dispute that that
9 "pro" means anything as Mr. Runkle has it interpreted. Pro is
10 a term of art used in the industry to talk about tracking
11 records. But in any event, we dispute that there's any recent
12 conduct, certainly nothing since 2013.

13 And so from 2013 to present, there is actually no evidence
14 before the Court of anything illegal going on at SK. And what
15 I want to do is, frankly, just open up to whatever questions
16 Your Honor has to satisfy Your Honor that Mr. Patel is not out
17 there committing violations.

18 Mr. Lassiter is here. He's willing to go forward and serve
19 as a monitor for the Court. We've talked to him about giving
20 reports back to the Court about what's ongoing with SK, to
21 assure that there's no ongoing problems there. And we would
22 ask that Mr. Patel, who is now an integral part with respect to
23 the company -- he is now a vice president. He wasn't vice
24 president back when he first stated. He is now a vice
25 president, and we ask that he be given the opportunity to

1 satisfy the Court through this monitor. In other words, have
2 Mr. Lassiter act as the Court's eyes and ears and go back and
3 independently verify. He's not a high-priced -- I think Mr.
4 Runkle's explanation was he's a high-priced expert. At this
5 point, he's here to audit. He's been picked in the past. He's
6 certainly got the credentials to conduct this type of audit.
7 And we want to assure the Court that there's nothing untoward
8 going on at SK, or certainly nothing untoward occurring by
9 Sitesh Patel.

10 All of these allegations relate to old conduct. There's
11 nothing new except for this one complaint, and we dispute it at
12 2015. There's nothing new. And we simply want to emphasize to
13 the Court that this isn't an instance where someone has done
14 something while they're out on bond.

15 And for that reason, Your Honor -- so I invite Your Honor
16 to pose questions to me regarding what it would do to satisfy
17 Your Honor to make sure that he's not out there committing, you
18 know, that he's not a danger to the public.

19 THE COURT: Thank you.

20 MR. MCMULLEN: Your Honor, could I add one point as to
21 SK? There's an overlap in the issues as to most of those
22 points. However, there's one thing that I think should be
23 pointed out, and it came at the very end of Dr. Deuster's
24 testimony, and that when the Court and Mr. Hall were inquiring
25 as to her knowledge of what's been going on at SK Labs after

1 2013, there was some discussion about what organizations would
2 be appropriate to determine whether they're providing the right
3 products or good products in the market, and there was a
4 discussion of WADA.

5 THE COURT: Right.

6 MR. MCMULLEN: Dr. Royster herself at that point
7 mentioned as one of the approved organizations that would be
8 reliable as --

9 THE COURT: I'm sorry, who?

10 MR. MCMULLEN: Dr. Royster just now mentioned
11 Informed-Choice.

12 THE COURT: Deuster.

13 MR. MCMULLEN: Deuster. I'm sorry. Dr. Deuster
14 mentioned Informed-Choice as someone that she would find
15 reliable. And what's important here, and this was provided in
16 Exhibit C to SK Labs' response, is that that's exactly what SK
17 Labs did. They sought out a review by Informed-Choice. Put in
18 the papers what that review involved. It involved an on-site
19 visit. It involved swabs being taken. And they maintained
20 that registration status with that organization until the
21 indictment was filed in the case, at which point, and the
22 letter that I provided to the Court, is that the only reason
23 that they lost that status from Informed-Choice was as a result
24 of the indictment and nothing else. And so I think that that
25 is an indication that the Government's own witness has

1 identified an organization that found that -- that would be an
2 appropriate way to know that what the company is doing now is
3 okay and they did comply with the, in the past, the
4 registration requirements of that organization.

5 THE COURT: So what you're throwing to me is the
6 possibility of imposing that as a condition, is having
7 Informed-Choice continue to monitor the activities at SK Labs?

8 MR. MCMULLEN: Your Honor, I don't think that I can do
9 that. I think that the best next alternative is to provide
10 someone --

11 THE COURT: No, but I can do that.

12 MR. MCMULLEN: -- who is going to do it.

13 THE COURT: So are you saying that that's something
14 that you'd agree to or that's a condition you could live with
15 or --

16 MR. MCMULLEN: Your Honor, this is the issue. The
17 letter that was provided by Informed-Choice in response to the
18 indictment is very strongly worded, in which they said, look,
19 we have our own necessity as our organization to protect our
20 own reputation, and because you've been indicted, you're out.
21 We're not going to be involved with you.

22 THE COURT: Okay.

23 MR. MCMULLEN: So I don't think that they would be
24 willing to be involved in our organization anymore, but solely
25 as a result of the indictment, notwithstanding SK passing all

1 the test requirements.

2 THE COURT: Thank you.

3 MR. MCMULLEN: Thank you, Your Honor.

4 MR. RUNKLE: I just have a few responses to that, Your
5 Honor.

6 The first is that, obviously, if we believe that they were
7 committing crimes right now in violation of the pre-trial
8 release, we would be seeking detention. That's not what we're
9 seeking. We're seeking a very measured response to what we
10 think is a need that's out there. The public needs to be
11 assured that these companies are not continuing the same
12 conduct.

13 The second response that I have generally to Mr. Hall and
14 Mr. McMullen is that they haven't sought to explain in these
15 audits the problem of the fraud that Mr. Patel committed both
16 on the company and on consumers. So, as an example of what
17 happened, USPlabs wanted SK Labs to use a new substance called
18 cynanchum auriculatum in the last formulation of OxyElite Pro.
19 That substance, Jacob Geissler agreed with the Chinese supplier
20 that what they were actually having shipped to the United
21 States was not cynanchum auriculatum extract but it was just
22 the ground up plant of cynanchum auriculatum, which wouldn't
23 have any of the properties of the concentrated extract. It
24 wouldn't actually have the active ingredient. And so that new
25 substance, there's no way to test it. There's no reference

1 standard. That's the problem with these audits.

2 So when that fraud occurred, they go, hey, we have this new
3 substance, it's a plant extract, let's put it in OxyElite Pro.
4 And there's no way to handle that kind of conduct in what these
5 audits are doing unless they're prohibited from using certain
6 ingredients or new ingredients or unless these audits are doing
7 new dietary ingredient checks to make sure that nothing there
8 is something that there isn't a reference standard for and
9 isn't being tested every day. And I just have no confidence
10 that that will actually accomplish that.

11 THE COURT: So even if we do audits on a regular
12 basis, if they keep adding new ingredients, there's no way to
13 keep that from happening?

14 MR. RUNKLE: It depends on what the ingredients are.

15 THE COURT: Right.

16 MR. RUNKLE: And these companies love to use new,
17 wham-bang, hey, here's this extract that's going to, you know,
18 help you lose weight and grow hair, you know, whatever it is,
19 right? And so that's the fundamental problem. And that's the
20 fundamental problem that Mr. Patel has -- he's engaged in fraud
21 and his co-conspirators have engaged in fraud in exactly that
22 area, about the identities of these ingredients. And, you
23 know, the value-added thing about cynanchum auriculatum is that
24 Jacob Geissler knew that it could have liver toxicity
25 associated with it. Now, I don't think they put enough of it

1 in the product to actually hurt people's livers, but it was a
2 fraud coming and going, and it affects the safety of the
3 community when that kind of activity is going on. And I don't
4 believe these audits can properly handle that unless the audits
5 are so stringent that they are -- that they're prohibiting the
6 uses of those types of ingredients.

7 Thank you, Your Honor.

8 THE COURT: Thank you.

9 MR. HALL: Your Honor, may I response to his -- that
10 point?

11 THE COURT: Yes.

12 MR. HALL: Thank you. Your Honor, there is -- that's
13 inaccurate about the product, all right? They can test for new
14 ingredients. It's done. It's sent out to an outside service.
15 It can be tested. And so there is a way to monitor these types
16 of activities, and it doesn't depend at all on what the
17 representation of Mr. Sitiesh Patel or anyone else is. It's an
18 independent analysis of the substance that comes in. It's done
19 according to the general manufacturing practices and
20 procedures. Mr. Lassiter, we've spoken with him regarding
21 this, and there's testing done when any new product comes in,
22 so new -- any new ingredient arrives, and so it's --

23 THE COURT: Well, what about the old product where
24 they change the formula?

25 MR. HALL: Well, if they're changing the formula and

1 they're adding a new ingredient, then it's still a new
2 ingredient that they can test. And so we certainly --

3 THE COURT: That's encompassed by the audit as well?

4 MR. HALL: That certainly can be encompassed by such
5 an audit, Your Honor.

6 THE COURT: Uh-huh. What else?

7 MR. HALL: That's it. Thank you, Your Honor.

8 THE COURT: Thank you.

9 All right. I'll take this matter under advisement. I'll
10 try to get a decision out rather quickly.

11 Any other matters for the Government?

12 MR. RUNKLE: Nothing else, Your Honor.

13 THE COURT: For the Defense?

14 MR. HALL: No, Your Honor.

15 MR. MCMULLEN: No, Your Honor. Thank you.

16 THE COURT: Thank you. We stand adjourned.

17 (Proceedings concluded at 10:19 a.m.)

18 --oOo--

19

20 CERTIFICATE

21 I certify that the foregoing is a correct transcript from
22 the digital sound recording of the proceedings in the above-
entitled matter.

23 **/s/ Kathy Rehling**

09/08/2016

24

25 Kathy Rehling, CETD-444
Certified Electronic Court Transcriber

Date

INDEX

PROCEEDINGS

3

WITNESSES

Government's Witnesses

Direct Cross Redirect Recross Court

Yamira Quinones

13

18

Leanne Sparling

19

27

Patty Deuster

31

42

EXHIBITS

-none-

RULINGS - Taken Under Advisement

65

END OF PROCEEDINGS

65

INDEX

66